

of the rejection.

At page 5, lines 1-7 of the office action, the Examiner argues:

The fact that Applicants show that pretreating rabbits with IT9302 prevents them from mortality, does not demonstrate that the disease is prevented. "Prevention" is described as a general term for the effort to prevent disease from occurring in unaffected individuals, as opposed to the treatment of individuals who are already affected; thus applicants have not demonstrated that the recited diseases are prevented to the point that unaffected individuals do not get them. Thus, a method of preventing a disease by a substance which has at least one of the properties listed in a-k of claim 49 is not enabled.

New claim 80 is directed to exactly what the examiner concedes we prevented:

A method of preventing death due to pancreatitis which comprises administering to a subject an effective amount of a pharmaceutical composition according to claim 41.

New claim 81 is directed to:

A method of preventing development of acute respiratory-distress like syndrome which comprises administering to a subject an effective amount of a pharmaceutical composition according to claim 41.

Basis for this alternative "prevention" recitation appears at page 48, lines 20-25:

IT9302 downregulates TNF- α and IL-8 production in a model of bile acid induced acute pancreatitis, and blocks neutrophil infiltration in lungs of these treated rabbits, thereby preventing the development of ARDS-like syndrome in these animals, resulting in a reduction of mortality from 60% to 0% after 12 hours.

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In support of claims 80 and 81, we enclose a copy of a preprint of Osman, et al., Profiles of Pro-Inflammatory Cytokines in the Serum of Rabbits after Experimentally Induced Acute Pancreatitis, to be published in cytokine in 2002, and describing the effect of IT9302 in rabbits.

2. New Claim 82

New claim 82 is responsive to OA S5a, questioning the recitation of "methionine-s-oxide" and "L-Dab" in the claim. The markush groups of 82 leave out these species.

Respectfully submitted,

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Enclosure

-Osman article

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